DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

WARNING LETTER
2000-DT-19

April 12, 2000

Ms. Elaine H. Houlihan
President
Houlihan's Culinary Traditions, Ltd.
70 Squirrel Road
Auburn Hills, MI 48326

Dear Ms Houlihan:

An inspection of your acidified food processing operation was conducted on September 13 - October 12,1999 by Investigators Michael V. Owens and Darren S. Morgan. At the conclusion of the inspection you were presented with a Form FDA-483, Inspectional Observations, listing serious deviations from the Current Good Manufacturing Practice (CGMP) regulations for acidified food manufacturers [Title 21, Code of Federal Regulations (CFR), Parts 108.25 and 114]. These deviations cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act),

Specifically our investigators found the following:

1. Failure to register with the Food and Drug Administration.
   21 CFR 108.2(c)(1)
   We acknowledge receipt of the completed registration dated 12/1/99.

2. Failure to file information on the scheduled processes for each acidified food.
   21 CFR 108.25(c)(2)

3. Failure to prepare and maintain files on a current procedure for recalling product that may be injurious to health; for identifying, collecting, warehousing, for controlling products and determining the effectiveness of the recall, for notifying the Food and Drug Administration, and for implementing recall programs.
   21 CFR 108.25(e)

4. Failure to have an operating supervisor attend and satisfactorily complete a school approved by the FDA for instruction in various subjects pertaining to the processing of acidified foods.
   21 CFR 108.25(f) and 114.10

   You informed our investigators that someone would attend the school conducted by [redacted] Please provide documentation that someone attended and completed this school.

5. Failure to employ sufficient control, including frequent testing and recording of results, to ensure that the finished equilibrium pH values are no higher than 4.6. 21 CFR 114.80(a)(2)

   a. There were no measurements of finished equilibrium pH. Your procedure was to test the pH on one jar of product immediately after filling while it was still at a high temperature. Equilibrium pH is achieved when all particles of food in the product have equilibrated to the same pH level. This may take several hours, depending on the size of particles of low-acid foods in the products. In addition, measuring pH while the product is above room temperature (68-86°F) will give you a lower pH value. It was observed that the pH meter was not adjusted to the temperature of the product. In addition, the buffers used to standardize the pH meter were not at this elevated temperature.

   b. There was only one pH measurement taken for a production day. Your firm makes several batches of product each day. Each batch may have a different pH depending on the accuracy of the formulation control. Procedures must be established to ensure that the pH of each batch is properly controlled.

   c. The buffer solutions used to calibrate the pH meter were expired. We understand that new buffers were purchased.

   You should provide us with your procedures for the pH testing of products during and after processing to ensure that the pH of each batch is properly controlled and provide the pH measuring procedures utilized to ensure that pH measurements are accurate.

6. Failure to have processes established by a qualified person. 21 CFR 114.83

   You indicated that your processes were evaluated by [redacted] from [redacted] However, there was no written communication which delineated critical factors which must be controlled to ensure proper pH control or any indication that [redacted] actually evaluated your processing and control procedures to determine which factors are critical. When these factors have been identified, they must be filed with FDA on FDA Form 2541a.

7. Failure to maintain proper processing and production records. 21 CFR 114.100(b)

   Your records did not document whether the pH of each batch was properly controlled. There were no records of finished equilibrium pH measurements. At such time as you have your processes properly established, you must devise records to record testing results and other information for those factors deemed to be critical. These records must include pH measurements and may include such things as formulation control, ingredient pH, etc. Records must also contain sufficient information, such as product code, date, container size, and product to permit a public health hazard evaluation of the processes applied to each lot, batch or other portion of production.

8. Your procedure for determining the integrity of the container closures was to test the tightness by hand. While this may be an appropriate method, we suggest that you contact your container supplier and determine the appropriate method for testing and examinations to ensure that the product is protected from leakage and contamination. 21 CFR 114.80(a)(4)

The above is not intended to be an all-inclusive list of deviations which may exist at your firm. It is your responsibility to ensure that your firm is in full compliance with the Act and regulations promulgated thereunder.

We request that you take prompt action to correct these deviations. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

For your information, our Center for Food Safety and Nutrition (CFSAN) has reviewed the product formulations covered during the last inspection. They have indicated that four are definitely acidified foods, and that all but one of the others are probably acidified.

The four definite products are:	The probably acidified products are:
- Fungi Pepe Verde Sauce	Insalata Pomodoro Sauce
- Dolce Piselli Sauce	Aglio E Aglio SAuce
- Bread Dipping Sauce	Semplice Pomodoro Sauce
- Formaggio Sauce	Aglio Arrostito Sauce
	Basilico E Aglio Sauce
	Arrabiato Sauce

The product Baciato Dal Sole Sauce is of concern if the three added ingredients, a pearl onion, three garlic cloves, and one bay leaf, are fresh (versus dry), and therefore low-acid. There is possibility that C. botulinum might grow and produce toxin unless they are acidified before being added to the sauce. If they are fresh and are acidified, then the finished product would also be an acidified food. This product should be studied as the others listed above, to ensure the equilibrium pH is no higher than 4.6.

Finally, a review of your product list shows other products which may be acidified, and your co-pack business, making products to a specific customer recipe, could also include acidified products.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time in which the corrections will be completed.

Your response should be directed to this office to the attention of Mr. Melvin O. Robinson, Compliance Officer. (313) 226-6260 Extension 128

Sincerely yours,

John P. Dempster

for Raymond V. Mlecko
District Director
Detroit District